



## Arbutus Reports First Quarter 2024 Financial Results and Provides Corporate Update

May 2, 2024

**End-of-treatment data from two Phase 2a combination clinical trials with imdusiran to be presented at the EASL Congress in June 2024**

**Preliminary data from the single-dose portion of the AB-101-001 clinical trial show that AB-101 was generally well-tolerated and bound to the receptor target in healthy subjects**

**Court provides claim construction ruling in ongoing patent infringement lawsuit against Moderna; Court date scheduled for April 21, 2025**

**Strong financial position – expected cash runway extended through the second quarter of 2026**

**Conference Call and Webcast Today at 8:45 AM ET**

WARMINSTER, Pa., May 02, 2024 (GLOBE NEWSWIRE) -- Arbutus Biopharma Corporation (Nasdaq: ABUS) ("Arbutus" or the "Company"), a clinical-stage biopharmaceutical company leveraging its extensive virology expertise to develop a functional cure for people with chronic hepatitis B virus (cHBV) infection, today reports first quarter 2024 financial results and provides a corporate update.

"We continued to make progress in the first quarter of 2024 in advancing our pipeline of HBV assets," said Michael J. McElhaugh, Interim President and Chief Executive Officer of Arbutus Biopharma. "Along with imdusiran, which we see as a potential cornerstone therapeutic, we believe an immune modulator also plays an important role in the treatment regimen to functionally cure cHBV. In pursuit of this goal, we have initiated our third Phase 2a trial combining imdusiran with an immune modulator and are reporting the first part of the Phase 1a/1b trial with AB-101, our oral proprietary PD-L1 checkpoint inhibitor. The end-of-treatment data from our two ongoing Phase 2a combination trials with imdusiran and other immune modulators will be presented at the EASL conference upcoming in June. With an expected cash runway now through the second quarter of 2026, we are well funded to move our existing clinical trials forward to achieve meaningful data and advance into a later stage clinical trial."

### Clinical Development Update

#### Imdusiran (AB-729, RNAi Therapeutic)

- AB-729-201 is a Phase 2a clinical trial that is evaluating the safety, tolerability and antiviral activity of the combination of imdusiran, nucleos(t)ide analogue (NA) therapy and pegylated interferon alfa-2a (IFN) in patients with cHBV. [Preliminary data presented at the EASL Congress](#) in June 2023 suggest that the addition of IFN to imdusiran was generally well-tolerated and appears to result in continued HBsAg declines in some patients. End-of-treatment data from this trial will be shared at the upcoming EASL Congress in June.
- AB-729-202 is a Phase 2a clinical trial that is evaluating the safety and immunogenicity of imdusiran, NA therapy and Barinthus Bio's VTP-300, an HBV antigen-specific immunotherapy. [Preliminary data presented at AASLD – The Liver Meeting](#) in November 2023 showed that the combination of imdusiran and VTP-300 provided a meaningful reduction of HBsAg levels that are maintained well below baseline. End-of-treatment data from this portion of the trial will be shared at the upcoming EASL Congress in June.
- AB-729-202 was amended to include an additional cohort of 20 patients who will receive imdusiran plus NA therapy for 24 weeks followed by VTP-300 plus up to two low doses of nivolumab, an approved anti-PD-1 monoclonal antibody. Preliminary end-of-treatment data from this additional cohort are expected in the second half of 2024.
- AB-729-203 is a Phase 2a clinical trial evaluating the safety, tolerability and antiviral activity of imdusiran and NA therapy in combination with intermittent low doses of durvalumab, an approved anti-PD-L1 monoclonal antibody. Patients are being screened in this clinical trial. The clinical trial is designed to enroll 30 patients in three separate cohorts. All patients will receive 60mg of imdusiran every 8 weeks for 48 weeks and 2 doses of durvalumab given via IV infusion at pre-specified times during the imdusiran treatment period that will differ by cohort. After completion of treatment, all patients will be assessed for NA discontinuation and followed for at least 24 to 48 weeks.

#### AB-101 (Oral PD-L1 Inhibitor)

- AB-101-001 is a Phase 1a/1b double-blind, randomized, placebo-controlled clinical trial designed to investigate the safety, tolerability, pharmacokinetics (PK), and pharmacodynamics (PD) of single- and multiple-ascending oral doses of AB-101 for up to 28 days in healthy subjects and patients with cHBV. Part 1 of the clinical trial has enrolled four sequential cohorts of eight healthy subjects each (6 active:2 placebo) to date, each receiving a single dose of AB-101 at increasing dose levels up to 25mg or placebo. In this trial, AB-101 was generally well-tolerated with evidence of dose-dependent receptor occupancy. In the 25mg cohort, all five evaluable subjects showed evidence of receptor occupancy between 50-100%. Arbutus has moved into Part 2 of this clinical trial which evaluates multiple-ascending doses of AB-101 in healthy subjects

and expects to report preliminary data in the second half of this year.

## Corporate Updates

In a separate press release issued today, Arbutus announced that Michael J. Sofia, PhD will be retiring as Chief Scientific Officer at the end of 2024. Dr. Sofia is a co-founder of Arbutus and a globally recognized, Lasker award-winning antiviral drug discovery and development scientist.

### **The following abstracts were accepted for presentation at the EASL Congress 2024:**

**Abstract Title:** Imdusiran (AB-729) administered every 8 weeks in combination with 24 weeks of pegylated interferon alfa-2a in virally suppressed, HBeAg-negative subjects with chronic HBV infection leads to HBsAg loss in some subjects at end of IFN treatment.

**Authors:** Man-Fung Yuen, Jeong Heo, Ronald G Nahass, Grace Lai-Hung Wong, Tatiana Burda, Kalyan Ram Bhamidimarri, Tsung-Hui Hu, Tuan T Nguyen, Young-Suk Lim, Chi-Yi Chen, Stuart C Gordon, Jacinta Holmes, Wan-Long Chuang, Anita Kohli, Naim Alkhouri, Kevin Gray, Emily P. Thi, Elina Medvedeva, Timothy Eley, Sharie C Ganchua, Christina Iott, Elizabeth Eill, Christine L. Espiritu, Mark Anderson, Tiffany Fortney, Gavin Cloherty, Karen D Sims

**Abstract Title:** Imdusiran (AB-729) administered every 8 weeks for 24 weeks followed by the immunotherapeutic VTP-300 maintains lower HBV surface antigen levels in NA-suppressed CHB subjects than 24 weeks of imdusiran alone.

**Authors:** Kosh Agarwal, Man-Fung Yuen, Stuart Roberts, Gin-Ho Lo, Chao-Wei Hsu, Wan-Long Chuang, Chi-Yi Chen, Pei-Yuan Su, Sam Galhenage, Sheng-Shun Yang, Emily P. Thi, Katie Anderson, Deana Antonello, Elina Medvedeva, Timothy Eley, Tilly Varughese, Louise Bussey, Charlotte Davis, Antonella Vardeu, Christine L. Espiritu, Sharie C Ganchua, Christina Iott, Elizabeth Eill, Tom Evans, Karen D Sims

### **LNP Litigation Update:**

- With respect to the Moderna lawsuit, the claim construction hearing occurred on February 8, 2024. On April 3, 2024, the Court provided its [claim construction ruling](#), in which it construed the disputed claim terms and agreed with Arbutus' position on most of the disputed claim terms. Fact discovery is on-going and next steps include expert reports and depositions. A trial date has been set for April 21, 2025, and is subject to change.
- The lawsuit against Pfizer/BioNTech is ongoing and a date for a claim construction hearing has not been set.

Arbutus continues to protect and defend its intellectual property, which is the subject of the on-going lawsuits against Moderna and Pfizer/BioNTech. The Company is seeking fair compensation for Moderna's and Pfizer/BioNTech's use of its patented LNP technology that was developed with great effort and at a great expense, without which Moderna and Pfizer/BioNTech's COVID-19 vaccines would not have been successful.

## **Financial Results**

### **Cash, Cash Equivalents and Investments**

As of March 31, 2024, the Company had cash, cash equivalents and investments in marketable securities of \$137.9 million compared to \$132.3 million as of December 31, 2023. During the three months ended March 31, 2024, the Company used \$19.3 million in operating activities, which was offset by \$21.8 million of net proceeds from the issuance of common shares under its "at-the-market" offering program (ATM Program). During April 2024, the Company received an additional \$22.4 million of net proceeds under its ATM Program. The Company expects its 2024 net cash burn to range from between \$63 million to \$67 million, excluding any proceeds received from its ATM Program. The Company believes its cash, cash equivalents and investments in marketable securities including the additional net proceeds received under its ATM Program during April 2024, will be sufficient to fund its operations through the second quarter of 2026.

### **Revenue**

Total revenue was \$1.5 million for the three months ended March 31, 2024 compared to \$6.7 million for the same period in 2023. The decrease of \$5.2 million was due primarily to: i) a decrease in license revenue recognized related to the Company's progress towards the satisfaction of its performance obligations with respect to the licensing agreement with Qilu; and ii) a decrease in license royalty revenue from Alnylam due to lower sales of ONPATTRO in 2024 compared to 2023.

### **Operating Expenses**

Research and development expenses were \$15.4 million for the three months ended March 31, 2024 compared to \$18.3 million for the same period in 2023. The decrease of \$2.9 million was due primarily to the discontinuation of the Company's AB-161 and coronavirus programs in September 2023 as part of its efforts to focus its pipeline on its lead HBV product candidates, partially offset by an increase in clinical expenses for the Company's multiple imdusiran Phase 2a clinical trials. General and administrative expenses were \$5.3 million for the three months ended March 31, 2024 compared to \$5.6 million for the same period in 2023. The decrease of \$0.3 million was due primarily to a decrease in non-cash stock-based compensation expenses.

### **Net Loss**

For the three months ended March 31, 2024, the Company net loss was \$17.9 million, or a loss of \$0.10 per basic and diluted common share, as compared to a net loss of \$16.3 million, or a loss of \$0.10 per basic and diluted common share, for the three months ended March 31, 2023.

### **Outstanding Shares**

As of March 31, 2024, the Company had approximately 180.2 million common shares issued and outstanding. During April 2024, the Company issued an additional 7.8 million common shares under its ATM program. In addition, the Company had approximately 22.6 million stock options and unvested restricted stock units outstanding as of March 31, 2024. Roivant Sciences Ltd. owned approximately 20% of our outstanding common shares as of April 30, 2024.

**UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF LOSS**  
(in thousands, except share and per share data)

	Three Months Ended March 31,	
	2024	2023
<b>Revenue</b>		
Collaborations and licenses	\$ 939	\$ 5,509
Non-cash royalty revenue	593	1,178
<b>Total revenue</b>	<b>1,532</b>	<b>6,687</b>
<b>Operating expenses</b>		
Research and development	15,403	18,275
General and administrative	5,312	5,552
Change in fair value of contingent consideration	180	273
<b>Total operating expenses</b>	<b>20,895</b>	<b>24,100</b>
Loss from operations	(19,363)	(17,413)
Other income (loss)		
Interest income	1,545	1,268
Interest expense	(44)	(198)
Foreign exchange gain	(13)	4
Total other income	1,488	1,074
<b>Net loss</b>	<b>\$ (17,875)</b>	<b>\$ (16,339)</b>
<b>Loss per share</b>		
Basic and diluted	\$ (0.10)	\$ (0.10)
<b>Weighted average number of common shares</b>		
Basic and diluted	175,625,552	161,643,404
<b>Comprehensive loss</b>		
Unrealized gain on available-for-sale securities	50	854
<b>Comprehensive loss</b>	<b>\$ (17,825)</b>	<b>\$ (15,485)</b>

**UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS**  
(in thousands)

	March 31, 2024	December 31, 2023
Cash, cash equivalents and marketable securities, current	\$ 129,240	\$ 126,003
Accounts receivable and other current assets	6,632	6,024
<b>Total current assets</b>	<b>135,872</b>	<b>132,027</b>
Property and equipment, net of accumulated depreciation	4,414	4,674
Investments in marketable securities, non-current	8,677	6,284
Right of use asset	1,327	1,416
<b>Total assets</b>	<b>\$ 150,290</b>	<b>\$ 144,401</b>
Accounts payable and accrued liabilities	\$ 8,247	\$ 10,271
Deferred license revenue, current	11,547	11,791
Lease liability, current	502	425
<b>Total current liabilities</b>	<b>20,296</b>	<b>22,487</b>
Liability related to sale of future royalties	6,396	6,953
Contingent consideration	7,780	7,600
Lease liability, non-current	1,181	1,343
Total stockholders' equity	114,637	106,018
<b>Total liabilities and stockholders' equity</b>	<b>\$ 150,290</b>	<b>\$ 144,401</b>

**UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(in thousands)

	Three Months Ended March 31,	
	2024	2023
Net loss	\$ (17,875)	\$ (16,339)

Non-cash items	1,439	1,372
Change in deferred license revenue	(244)	(4,104)
Other changes in working capital	(2,615)	(8,230)
<b>Net cash used in operating activities</b>	<b>(19,295)</b>	<b>(27,301)</b>
<b>Net cash provided by investing activities</b>	<b>11,694</b>	<b>16,678</b>
Issuance of common shares pursuant to the Open Market Sale Agreement	21,765	19,862
Cash provided by other financing activities	2,665	555
<b>Net cash provided by financing activities</b>	<b>24,430</b>	<b>20,417</b>
Effect of foreign exchange rate changes on cash and cash equivalents	(13)	4
Increase in cash and cash equivalents	16,816	9,798
Cash and cash equivalents, beginning of period	26,285	30,776
Cash and cash equivalents, end of period	43,101	40,574
Investments in marketable securities	94,816	137,944
<b>Cash, cash equivalents and marketable securities, end of period</b>	<b>\$ 137,917</b>	<b>\$ 178,518</b>

### **Conference Call and Webcast Today**

Arbutus will hold a conference call and webcast today, Thursday, May 2, 2024, at 8:45 AM Eastern Time to provide a corporate update. To dial-in for the conference call by phone, please register using the following link: [Registration Link](#). A live webcast of the conference call can be accessed through the Investors section of Arbutus' website at [www.arbutusbio.com](http://www.arbutusbio.com).

An archived webcast will be available on the Arbutus website after the event.

### **About imdusiran (AB-729)**

Imdusiran is an RNA interference (RNAi) therapeutic specifically designed to reduce all HBV viral proteins and antigens including hepatitis B surface antigen, which is thought to be a key prerequisite to enable reawakening of a patient's immune system to respond to the virus. Imdusiran targets hepatocytes using Arbutus' novel covalently conjugated N-Acetylgalactosamine (GalNAc) delivery technology enabling subcutaneous delivery. Clinical data generated thus far has shown single and multiple doses of imdusiran to be generally safe and well-tolerated, while also providing meaningful reductions in hepatitis B surface antigen and hepatitis B DNA. Imdusiran is currently in multiple Phase 2a clinical trials.

### **About AB-101**

AB-101 is our oral PD-L1 inhibitor candidate that we believe will allow for controlled checkpoint blockade while minimizing the systemic safety issues typically seen with checkpoint antibody therapies. Immune checkpoints such as PD-1/PD-L1 play an important role in the induction and maintenance of immune tolerance and in T-cell activation. Preclinical data generated thus far indicates that AB-101 mediates re-activation of exhausted HBV-specific T-cells from cHBV patients. We believe AB-101, when used in combination with other approved and investigational agents, could potentially lead to a functional cure in patients chronically infected with HBV. AB-101 is currently being evaluated in a Phase 1a/1b clinical trial.

### **About HBV**

Hepatitis B is a potentially life-threatening liver infection caused by the hepatitis B virus (HBV). HBV can cause chronic infection which leads to a higher risk of death from cirrhosis and liver cancer. Chronic HBV infection represents a significant unmet medical need. The World Health Organization estimates that over 290 million people worldwide suffer from chronic HBV infection, while other estimates indicate that approximately 2.4 million people in the United States suffer from chronic HBV infection. Approximately 820,000 people die every year from complications related to chronic HBV infection despite the availability of effective vaccines and current treatment options.

### **About Arbutus**

Arbutus Biopharma Corporation (Nasdaq: ABUS) is a clinical-stage biopharmaceutical company leveraging its extensive virology expertise to identify and develop novel therapeutics with distinct mechanisms of action, which can be combined to provide a functional cure for patients with chronic hepatitis B virus (cHBV). We believe the key to success in developing a functional cure involves suppressing HBV DNA, reducing surface antigen, and boosting HBV-specific immune responses. Our pipeline of internally developed, proprietary compounds includes an RNAi therapeutic, imdusiran (AB-729), and an oral PD-L1 inhibitor, AB-101. Imdusiran has generated meaningful clinical data demonstrating an impact on both surface antigen reduction and reawakening of the HBV-specific immune response. Imdusiran is currently in three Phase 2a combination clinical trials. AB-101 is currently being evaluated in a Phase 1a/1b clinical trial. For more information, visit [www.arbutusbio.com](http://www.arbutusbio.com).

### **Forward-Looking Statements and Information**

This press release contains forward-looking statements within the meaning of the Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, and forward-looking information within the meaning of Canadian securities laws (collectively, forward-looking statements). Forward-looking statements in this press release include statements about our future development plans for our product candidates; the expected cost, timing and results of our clinical development plans and clinical trials with respect to our product candidates; our expectations with respect to the release of data from our clinical trials and the expected timing thereof; our expectations and goals for our collaborations with third parties and any potential benefits related thereto; the potential for our product candidates to achieve success in clinical trials; our expectations regarding our pending litigation matters; and our expected financial condition, including our anticipated net cash burn, the anticipated duration of cash runways and timing regarding needs for additional capital.

With respect to the forward-looking statements contained in this press release, Arbutus has made numerous assumptions regarding, among other things: the effectiveness and timeliness of preclinical studies and clinical trials, and the usefulness of the data; the timeliness of regulatory approvals; the continued demand for Arbutus' assets; and the stability of economic and market conditions. While Arbutus considers these assumptions to be

reasonable, these assumptions are inherently subject to significant business, economic, competitive, market and social uncertainties and contingencies, including uncertainties and contingencies related to patent litigation matters.

Additionally, there are known and unknown risk factors which could cause Arbutus' actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements contained herein. Known risk factors include, among others: anticipated pre-clinical studies and clinical trials may be more costly or take longer to complete than anticipated, and may never be initiated or completed, or may not generate results that warrant future development of the tested product candidate; Arbutus may elect to change its strategy regarding its product candidates and clinical development activities; Arbutus may not receive the necessary regulatory approvals for the clinical development of Arbutus' products; economic and market conditions may worsen; uncertainties associated with litigation generally and patent litigation specifically; and Arbutus and its collaborators may never realize the expected benefits of the collaborations; market shifts may require a change in strategic focus.

A more complete discussion of the risks and uncertainties facing Arbutus appears in Arbutus' Annual Report on Form 10-K, Arbutus' Quarterly Reports on Form 10-Q and Arbutus' continuous and periodic disclosure filings, which are available at [www.sedar.com](http://www.sedar.com) and at [www.sec.gov](http://www.sec.gov). All forward-looking statements herein are qualified in their entirety by this cautionary statement, and Arbutus disclaims any obligation to revise or update any such forward-looking statements or to publicly announce the result of any revisions to any of the forward-looking statements contained herein to reflect future results, events or developments, except as required by law.

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